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RCB  
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OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

323C

MEMORANDUM

SUBJECT: Ronilan on Stone Fruit and Lettuce; PP#962204  
EPA Reg.#7969-EUP-13

FROM: Robert Coberly  
Toxicology Branch, HED (TS-769) *16 5/6/81*

TO: Henry Jacoby (21)  
Registration Division (TS-767)

In our September 13, 1979 review of Ronilan for use on stone fruit and lettuce, we judged the existing toxicity data base as being sufficient to support the requested temporary tolerances even though the projected TMRC would exceed the PADI by a considerable margin. This decision was based on the calculated assumption that the PADI which is based on a 90-day dog NOEL of 300 ppm and 2000 fold safety factor, would be substantially increased with the receipt of the ongoing 6-month dog feeding.

This change was anticipated due to the projected increase in the NOEL from 300 ppm to between 600-900 ppm and the reduction of the safety factor to 1000 fold. This combination would place the TMRC of the requested and published tolerances under 100% of the new ADI. However, on reconsideration, it appears evident that this type decision constitutes a policy setting mode (supporting an EUP where the resulting TMRC exceeds the PADI) which cannot be executed at this level of authority.

Accordingly, we request you to adjust the requested temporary tolerances so that the cumulative TMRC does not exceed 100% of the PADI.

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TMRC - Theoretical Maximal Residue Contribution

PADI - Provisional Acceptable Daily Intake